Application No. 10/773,775 Docket No.: IQA-00901 Amendment G

AMENDMENTS TO THE CLAIMS

(Currently amended) A sample processing tubule, comprising:
 a proximal end having an opening through which a sample is introducible;
 a distal end; and

at least a first segment containing at least one substance capable of specific binding to a preselected component of a sample when the sample is added to the tubule, a second segment distal to the first segment and containing a wash reagent, and a third segment distal to the second segment and containing an amplification reagent, each of which segments is:

defined by the tubule;

fluidly isolated, at least in part by a breakable-fluid-tight seal formed

by a bonding of opposed wall portions of the tubule to one

another such that:

- (a) the seal is broken by application of fluid pressure on a

 segment that is fluidly isolated in part by the seal;

 and
- (b) the seal is capable of being clamped where the opposed
 wall portions of the tubule are bonded, without
 breaking the seal, to prevent the seal from being
 broken by application of fluid pressure on a segment
 that is fluidly isolated in part by the seal;

Application No. 10/773,775 Docket No.: IQA-00901

Amendment G

so expandable as to receive a volume of fluid expelled from another

segment; and

so compressible as to contain substantially no fluid when so compressed.

- (Original) The tubule of claim 1, wherein at least a portion of the tubule is transparent.
- (Original) The tubule of claim 1, further comprising at least one pressure gate in fluid communication with at least one segment.
- 4. (Original) The tubule of claim 1, further comprising at least one filter in the tubule.
- (Canceled)
- (Previously presented) The tubule of claim 1, wherein the preselected component is nucleic acid.
- 7. (Original) The tubule of claim 6, wherein the substance capable of specific binding to nucleic acid includes at least one of an antibody, nucleic acid, peptide nucleic acid, phosphothioate nucleic acid, silica coated surface, electrostatically charged surface, and enzyme.
- (Original) The tubule of claim 7, wherein the substance capable of specific binding to nucleic acid has a preselected amino acid or base sequence.
- 9. (Previously presented) The tubule of claim 1, wherein the substance comprises at least one of a receptor, a ligand, an antibody, an antigen, a nucleic acid probe, a peptide nucleic acid probe, a phosphothioate nucleic acid probe, a bacteriophage, silica, and an electrostatic charged surface.

Docket No.: IOA-00901 Amendment G

10. (Previously presented) The tubule of claim 1, wherein the substance is capable of specific binding to a preselected component of at least one of bacteria, virus, parasite, cells, nucleic acid, and spores.

- 11. (Withdrawn) The tubule of claim 10, wherein the substance is capable of specific binding to a preselected component of at least one of Yersinia pestis, Francisella tularensis, Listeria monocytogenes, Bacillus anthracis, Escherichia coli, Salmonella enteritidis, Campylobacter pylori, Campylobacter jejuni Clostridium perfringens, Staphylococcus aureus, Haemophilus influenzae, Streptococcus pneumoniae, Neisseria meningitides, Vibrio cholerae, Mycobacterium tuberculosis, and Mycobacterium leprae.
- 12. (Withdrawn) The tubule of claim 10, wherein the substance is capable of specific binding to a preselected component of at least one of human immunodeficiency virus 1, human immunodeficiency virus 2, influenza virus, yellow fever virus, dengue virus, hepatitis B virus, hepatitis C virus, cytomegalovirus, Epstein Barr virus, West Nile virus, hantavirus, and small pox.
- 13. (Withdrawn) The tubule of claim 10, wherein the substance is capable of specific binding to a preselected component of at least one of Plasmodium falcinarum. Plasmodium vivax, Plasmodium ovale, Plasmodium malariae, Leishmania tropica, Leishmania donovani, Leishmania infantum, Leishmania major, Leishmania mexicana, Leishmania chagasi, Leishmania brasiliensis, and Leishmania amazoniensis.

14. (Previously presented) The tubule of claim 1, wherein the substance capable of specific binding to a preselected component of a sample is coupled to a solid substrate.

- 15. (Original) The tubule of claim 14, wherein the substance forms a coating on the solid substrate.
- 16. (Original) The tubule of claim 14, wherein the solid substrate comprises at least one of beads, a pad, a filter, a sheet, an electrostatic surface, and a portion of a tubule wall surface.
- 17. (Original) The tubule of claim 14, wherein the substrate comprises at least one of silica beads, magnetic beads, silica magnetic beads, glass beads, nitrocellulose colloid beads, and magnetized nitrocellulose colloid beads.
- 18. (Original) The tubule of claim 14, wherein the substance comprises silica, and the substrate comprises a filter or a sheet.
- 19. (Withdrawn) The tubule of claim 14, wherein the substrate comprises a pad formed at least in part from an absorbent material comprising at least one of paper, film, filter, foam, mesh, and fiber matrix.
- 20. (Withdrawn) The tubule of claim 14, wherein the substrate is coupled to a tubule wall.
- (Withdrawn-Previously presented) The tubule of claim 1, further comprising a 21. solid substrate which comprises a pad formed at least in part from an absorbent material comprising at least one of paper, film, filter, foam, mesh, and fiber matrix.
- 22. (Canceled)

Docket No.: IOA-00901

- (Previously presented) The tubule of claim 1, further comprising a cap for closing the open end.
- 24. (Original) The tubule of claim 23, wherein the cap comprises a sample collection device including at least one of a swab, a stick, a scoop, an inoculation loop, a forceps, a dropper, a capillary tube, and a syringe.
- 25. (Original) The tubule of claim 24, wherein the sample collection device is so disposed in or on the cap as to transfer a sample from the device to the tubule when the cap is positioned in relation to the tubule to close the open end of the tubule.
- (Original) The tubule of claim 23, wherein the cap defines a cavity containing a chamber in fluid communication with the tubule.
- (Original) The tubule of claim 23, wherein the cap comprises a member defining an
 expandable chamber in the cap.
- 28. (Original) The tubule of claim 27, wherein a cap wall defines a vent.
- (Original) The tubule of claim 1, further comprising a frame to which the tubule is mounted.
- 30. (Previously presented) The tubule of claim 29, wherein the frame comprises an interface, the interface receiving the proximal end of the tubule.
- (Previously presented) The tubule of claim 30, wherein the interface also receives a
 cap, thereby sealing the proximal end of the tubule.
- (Previously presented) The tubule of claim 1, further comprising at least one of a diluent, suspension reagent, lysis reagent, neutralization reagent, elution reagent,

proteolytic reagent, glycosylase, nucleic acid, nuclease, ligase, alcohol, reverse

Docket No.: IOA-00901

transcription reagent, and germination reagent.

33. (Withdrawn) The tubule of claim 32, wherein the tubule comprises an elution

reagent that includes at least one of Tris buffer, water, and buffer suitable for

polymerase chain reaction.

34. (Withdrawn) The tubule of claim 32, wherein the tubule comprises a lysis reagent

that includes at least one of a guanidinium salt, a chaotropic salt, a red blood cell

lysis reagent, a detergent, a chelator, a spore germination reagent, sodium

hydroxide, proteinase K, DNase inhibitor, RNase, RNase inhibitor, anticoagulant,

coagulant, a protease, a germinant solution, and a surfactant.

35. (Withdrawn) The tubule of claim 32, wherein the tubule comprises a germination

reagent including heart brain infusion medium and at least one of L-alanine,

inosine, L-phenylalanine, L-Serine and L- proline.

Claims 36-43 (Canceled)

44. (Original) The tubule of claim 1, wherein the segments form a substantially linear

arrav.

45. (Original) The tubule of claim 1, wherein the segments form a contiguous array.

46. (Canceled)

47. (Currently amended) A sample processing tubule, comprising:

a substantially linear array of contiguous plurality of segments, each of which is:

defined by the tubule:

-7-

Application No. 10/773,775 Docket No.: IQA-00901 Amendment G

fluidly isolated, at least in part by a breakable-fluid-tight seal formed
by a bonding of opposed wall portions of the tubule to one
another such that;

(a) the seal is broken by application of fluid pressure on a segment that is fluidly isolated in part by the seal; and

(b) the seal is capable of being clamped where the opposed wall portions of the tubule are bonded, without breaking the seal, to prevent the seal from being broken by application of fluid pressure on a segment that is fluidly isolated in part by the seal;

separated from adjacent segments only by seals;

so expandable as to receive a volume of fluid expelled from another segment; and

so compressible as to contain substantially no fluid when so compressed;

- a segment contains at least one of a lysis reagent and a diluent;
- a segment contains at least a nucleic acid binding reagent;
- a segment contains at least a wash reagent;
- a segment contains at least a nucleic acid eluting regent; and
- a segment contains at least nucleic acid amplification reagents.

Claims 48-75 (Canceled)

Docket No.: IOA-00901

76. (Previously presented) The tubule of claim 1, wherein at least one of the reagents is

77. (Canceled)

78. (Previously presented) The tubule of claim 77, wherein the segments form a

substantially linear array.

79. (Previously presented) The tubule of claim 78, wherein the segments form a

contiguous array.

in a dry format.

80. (Previously presented) The tubule of claim 1, wherein the segments form a

contiguous and substantially linear array.

Claims 81-84 (Canceled)

87.

85. (Previously presented) The tubule of claim 1, further comprising at least a fourth

segment that (a) is distal to the second segment and (b) contains at least one of an

elution reagent, second wash regent, lysis reagent, reverse transcription reagent, a

nucleic acid, a nuclease, and glycosylase.

86. (Previously presented) The tubule of claim 1, further comprising at least a fourth

segment that (a) is proximal to the first segment and (b) contains at least one of a

germination reagent, suspension reagent, lysis reagent, neutralization reagent,

diluent, second wash reagent, elution reagent, nucleic acid, and proteolytic reagent.

(Previously presented) The tubule of claim 1, further comprising at least a fourth

segment that (a) is distal to the third segment and (b) contains at least one of a

second amplification reagent, a nuclease, a detection reagent, and a glycosylase.

-9-

88. (Previously presented) The tubule of claim 1, further comprising at least a fourth segment that (a) is distal to the first segment and (b) contains at least one of a diluent, suspension reagent, nucleic acid, lysis reagent, second wash reagent, a solid substrate, and alcohol.

- 89. (Previously presented) The tubule of claim 1, further comprising:
 - a fourth segment that (a) is proximal to the first segment and (b) contains at least one of a lysis reagent and a diluent; and
 - a fifth segment that (a) is distal to the second segment, (b) proximal to the third segment, and (c) contains an elution reagent.
- 90. (Previously presented) The tubule of claim 1, wherein the amplification reagent in the third segment comprises at least one of a nucleic acid polymerase and nucleotide triphosphates.
- 91. (Previously presented) The tubule of claim 1, wherein the at least one substance capable of specific binding to a preselected component of a sample in the first segment specifically binds nucleic acid.
- 92. (Currently amended) The tubule of claim 1, wherein the third [[a]]segment contains a detection reagent.
- 93. (Canceled)
- 94. (New) The tubule of claim 1, wherein the opposed wall portions of the tubule are left free of projections when the seal is broken.

95. (New) The tubule of claim 1, further comprising a chamber proximal to the opening, the chamber having a wall that comprises a barrier preventing liquid

escape and that defines a waste cavity in fluid communication with the opening.

Docket No.: IOA-00901

- (New) The tubule of claim 1, further comprising a chamber proximal to the 96. opening, the chamber having a wall that comprises a vent, and a member preventing liquid escape, and that defines a waste cavity in fluid communication with the opening.
- 97. (New) The tubule of claim 1, further comprising a chamber proximal to the opening, the chamber having a flexible membrane that prevents liquid escape, that defines a waste cavity in fluid communication with the opening, and that is deformable to increase the waste cavity volume.
- 98. (New) The tubule of claim 1, wherein a fourth segment distal to the third segment contains a detection reagent.
- 99. (New) The tubule of claim 1, wherein the substance capable of specific binding to a preselected component of the sample is, comprises, or is coupled to a solid phase substrate.
- 100. (New) The tubule of claim 99, wherein the wash reagent is capable of retaining the preselected component on the solid phase substrate while allowing removal of components of the sample not bound to the substrate.
- 101. (New) The tubule of claim 100, wherein the amplification reagent is capable of amplifying the preselected component of the sample.

102. (New) The tubule of claim 99, wherein the amplification reagent is capable of amplifying the preselected component of the sample.

Docket No.: IOA-00901

- 103. (New) The tubule of claim 99, further comprising a fourth segment that (a) is distal to the second segment, (b) is proximal to the third segment, and (c) contains an elution reagent capable of eluting the preselect component from the substrate.
- 104. (New) The tubule of claim 1, wherein the amplification reagent is capable of amplifying the preselected component of the sample.
- 105. (New) The tubule of claim 6, wherein:

the substance capable of specific binding to the preselected component of the sample comprises silica;

the silica is coupled to magnetic beads; and

the amplification reagent comprises at least one of a primer, a nucleotide triphosphate, and an amplification enzyme.

106. (New) The tubule of claim 1, wherein the segments are prepacked with their respective contents.